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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,319		Hidetoshi Uemura	UEMURA 5	6685

1444 7590 10/02/2002

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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	PAPER NUMBER
1636	16

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,319	UEMURA ET AL.	
	Examiner	Art Unit	
	daniel Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-33 and 35-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *11-33 and 35-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 11-15, 36 and 37, drawn to a nucleic acid encoding the polypeptide set forth as SEQ ID NO:2 or variants thereof, a vector and host cell comprising said nucleic acid encoding a polypeptide set forth as SEQ ID NO:2 or variants thereof, and a method of making said polypeptide set forth as SEQ ID NO:2 or variants thereof.

Group II, claim(s) 27-31, 35 and 41, drawn to the polypeptide set forth as SEQ ID NO:2 or variants thereof, compositions comprising said polypeptide set forth as SEQ ID NO:2 or variants thereof and methods of using said polypeptide set forth as SEQ ID NO:2 or variants thereof.

Group III, claim(s) 20-26, 32, 33, 38, 39, 42 and 43, drawn to an antibody against the polypeptide set forth as SEQ ID NO:2 or fragment thereof, methods of making, compositions comprising and methods of using said antibody.

Group IV, claim(s) 16-19, drawn to a non-human transgenic animal whose expression level of BSSP5 gene has been altered.

Group V, claim(s) 40, drawn to a method of screening for an inhibitor of serine protease enzyme activity.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The groups are united in that they are drawn to compositions and methods of making and using serine protease enzymes. However, serine proteases, including the specific embodiment of SEQ ID NO:2 (described in GenBank Accession No: X71877, and cited on the international search report), are known in the art and are therefore not novel. As the product claims do not represent a contribution over the prior art, the claims lack a special technical feature that is the same as or that corresponds to a special technical feature of the other claimed inventions. Thus,

there is no special technical feature linking the recited Groups, as would be necessary to fulfill the requirement for unity of invention.

The nucleic acids of Group I are related to the protein of Group II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay. Because the polypeptide set forth as SEQ ID NO:2 is not novel, the products lack a special technical feature and therefore do not meet the requirements for unity of invention.

The nucleic acids of Group I are related to the antibodies of Group III by virtue of the antibodies' binding affinity for a protein encoded by the nucleic acid. Although the nucleic acids and antibodies are related via the polypeptide encoded by the nucleic acids, which binds to the antibodies and can be used to make the antibodies by immunization, they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody can be made obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the nucleic acid may be used for processes other than the production of the protein, such as a nucleic acid hybridization assay. Because the polypeptide set forth as SEQ ID NO:2 is not novel, the products lack a special technical feature and therefore do not meet the requirements for unity of invention.

The polypeptides of Invention II are related to the antibodies of Invention III by virtue of binding affinity. Although the polypeptides and antibodies are related since the antibody binds to the polypeptide and can be raised by immunization with the polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody can be made obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the polypeptide may be used for processes other than the production of the antibody, such as a standard in an assay for the presence of the protein. Because the polypeptide set forth as SEQ ID NO:2 is not novel, the products lack a special technical feature and therefore do not meet the requirements for unity of invention.

The poly peptide of Invention II and nucleic acid of Invention I are related to the transgenic animal of Invention IV in that the animal can be produced using the nucleic acid of Invention I and comprises the polypeptide of Invention II. The animal is distinct from the polypeptide and nucleic acid, however, because they are physically and functionally distinct and the peptide and nucleic acid can be used for processes other than production of the transgenic animal, such as to raise antibodies, or screen for agents that bind to the protein or nucleic acid. Because the polypeptide set forth as SEQ ID NO:2 is not novel, the products lack a special technical feature and therefore do not meet the requirements for unity of invention.

The transgenic non-human animal of Group IV is not related to the antibody of Group I outside of over- or underexpression in the animal of the protein to which the antibody binds. Because the polypeptide set forth as SEQ ID NO:2 is not novel, the products lack a special technical feature and therefore do not meet the requirements for unity of invention.

Although the method of screening of Group V is related to some embodiments of the products of Groups I, II and IV in that the products can be used in the method of Group V, the inventions lack unity because the products can be used in processes that are materially different from the screening process of Group V. For example, the nucleic acids can be used in hybridization screening assays, the protein can be used to raise antibodies and the transgenic animals can be used in crossbreeding experiments. Because serine proteases and the polypeptide set forth as SEQ ID NO:2 is not novel, the products lack a special technical feature and therefore do not meet the requirements for unity of invention.

The antibody of Group III is unrelated to the method of screening of Group V outside of the antibodies affinity for one type of serine protease. Because serine proteases and the polypeptide set forth as SEQ ID NO:2 is not novel, the products lack a special technical feature and therefore do not meet the requirements for unity of invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
September 30, 2002

JAMES KETTER
PRIMARY EXAMINER